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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/016,528	10/30/2001	Bill Minshall	MINSH-001A	9635

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EXAMINER	
YAEN, CHRISTOPHER H	

ART UNIT	PAPER NUMBER
1642	3

DATE MAILED: 10/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/016,528	MINSHALL ET AL.	
	Examiner	Art Unit	
	Christopher H Yaen	1642	

-- The MAILING DATE of this communication appears n the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 October 2001* .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-39* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 3-4, 8-9, 12-14, and 16-17 drawn to a composition comprising an allogenic line of cancer cells providing at least one tumor associated ganglioside, at least one cytokine, and at least one heat shock protein, classified in class 424, subclass 93.1, for example. **Please note if this group is selected further select one tumor associated ganglioside (i.e. GD-2, GD-3, GM-2, GM-3, GD-1B, or GT-1B), one cytokine (i.e. GM-CSF, IL-2, IL-4, IL-12, or TNF-α), and one heat shock protein (i.e. HSP-60, -70, or –90) to be examined on the merits, and amend the claims accordingly, see below for explanation. THIS ELECTION SHOULD NOT BE CONSTRUED AS A SPECIES ELECTION.**

II. Claims 1,2 and 5 are drawn to a composition comprising an allogenic line of cancer cells providing at least two tumor associated gangliosides, at least one cytokine, and at least one heat shock protein, classified in class 435, subclass 33.2, for example. **Please note if this group is selected further select two tumor associated gangliosides (i.e. GD-2, GD-3, GM-2, GM-3, GD-1B, or GT-1B), one cytokine (i.e. GM-CSF, IL-2, IL-4, IL-12, or TNF-α), and one heat shock protein (i.e. HSP-60, -70, or –90) to b[illegible]xamined on the merits, and amend the claims accordingly, see**

below for explanation. THIS ELECTION SHOULD NOT BE CONSTRUED AS A SPECIES ELECTION.

III. Claims 1 and 6-7, are drawn to a composition comprising an allogenic line of cancer cells providing at least three tumor associated gangliosides, at least one cytokine, and at least one heat shock protein, classified in class 424, subclass 193.1, for example. **Please note if this group is selected further select three tumor associated gangliosides (i.e. GD-2, GD-3, GM-2, GM-3, GD-1B, or GT-1B), one cytokine (i.e. GM-CSF, IL-2, IL-4, IL-12, or TNF-α), and one heat shock protein (i.e. HSP-60, -70, or –90) to be examined on the merits, and amend the claims accordingly, see below for explanation. THIS ELECTION SHOULD NOT BE CONSTRUED AS A SPECIES ELECTION.**

IV. Claims 1 and 10-11, are drawn to a composition comprising an allogenic line of cancer cells providing at least one tumor associated ganglioside, at least two cytokine, and at least one heat shock protein, classified in class 424, subclass 85.1, for example. **Please note if this group is selected further select one tumor associated ganglioside (i.e. GD-2, GD-3, GM-2, GM-3, GD-1B, or GT-1B), two cytokines (i.e. GM-CSF, IL-2, IL-4, IL-12, or TNF-α), and one heat shock protein (i.e. HSP-60, -70, or –90) to be examined on the merits, and amend the claims accordingly, see below for explanation. THIS ELECTION SHOULD NOT BE CONSTRUED AS A SPECIES ELECTION.**

V. Claims 1 and 15 are drawn to a composition comprising an allogenic line of cancer cells providing at least one tumor associated ganglioside, at least one cytokine, at least one heat shock protein, and a leukocyte antigen classified in class 424, subclass 184.1, for example. **Please note if this group is selected further select one tumor associated ganglioside (i.e. GD-2, GD-3, GM-2, GM-3, GD-1B, and GT-1B), one cytokine (i.e. GM-CSF, IL-2, IL-4, IL-12, and TNF-α), and one heat shock protein (i.e. HSP-60, -70, and –90) to be examined on the merits, and amend the claims accordingly, see below for explanation. THIS ELECTION SHOULD NOT BE CONSTRUED AS A SPECIES ELECTION.**

VI. Claims 1 and 36-37, are drawn to a composition comprising an allogenic line of cancer cells providing at least one tumor associated ganglioside, at least one cytokine, at least one heat shock protein, and a melanoma – associated antigen classified in class 424, subclass 195.11, for example. **Please note if this group is selected further select one tumor associated ganglioside (i.e. GD-2, GD-3, GM-2, GM-3, GD-1B, or GT-1B), one cytokine (i.e. GM-CSF, IL-2, IL-4, IL-12, or TNF-α), one heat shock protein (i.e. HSP-60, -70, or –90), and one melanoma associated antigen (i.e. MAGE-1, MART-1, or GP-100) to be examined on the merits, and amend the claims accordingly, see below for**

explanation. THIS ELECTION SHOULD NOT BE CONSTRUED AS A SPECIES ELECTION.

VII. Claims 18, 20-21,25-26,29-31, and 33-35 are drawn to a method of inducing a systemic immune response comprising the steps of providing cells of at least one allogenic cell line providing at least one tumor associated ganglioside, one cytokine, one heat shock protein, and administering in an amount effective to induce a response to the antigen, classified in class 424, subclass 198.1, for example. **Please note if this group is selected further select one tumor associated ganglioside (i.e. GD-2, GD-3, GM-2, GM-3, GD-1B, or GT-1B), one cytokine (i.e. GM-CSF, IL-2, IL-4, IL-12, or TNF-α), and one heat shock protein (i.e. HSP-60, -70, or –90), to be examined on the merits, and amend the claims accordingly, see below for explanation. THIS ELECTION SHOULD NOT BE CONSTRUED AS A SPECIES ELECTION.**

VIII. Claims 18-19, and 22 are drawn to a method of inducing a systemic immune response comprising the steps of providing cells of at least one allogenic cell line providing at least <u>two</u> tumor associated gangliosides, one cytokine, one heat shock protein, and administering in an amount effective to induce a response to the antigen, classified in class 530, subclass 387.1, for example. **Please note if this group is selected further select two tumor associated gangliosides (i.e. GD-2, GD-3, GM-2, GM-3, GD-1B, or GT-1B), one cytokine (i.e. GM-CSF, IL-2, IL-4,**

IL-12, or TNF-α), and one heat shock protein (i.e. HSP-60, -70,or –90) to be examined on the merits, and amend the claims accordingly, see below for explanation. THIS ELECTION SHOULD NOT BE CONSTRUED AS A SPECIES ELECTION.

IX. Claims 18 and 23-24 are drawn to a method of inducing a systemic immune response comprising the steps of providing cells of at least three allogenic cell line providing at least one tumor associated ganglioside, one cytokine, one heat shock protein, and administering in an amount effective to induce a response to the antigen, classified in class 424, subclass 277.1, for example. **Please note if this group is selected further select three tumor associated gangliosides (i.e. GD-2, GD-3, GM-2, GM-3, GD-1B, or GT-1B), one cytokine (i.e. GM-CSF, IL-2, IL-4, IL-12, or TNF-α), and one heat shock protein (i.e. HSP-60, -70, or –90) to be examined on the merits, and amend the claims accordingly, see below for explanation. THIS ELECTION SHOULD NOT BE CONSTRUED AS A SPECIES ELECTION.**

X. Claims 18 and 27-28 are drawn to a method of inducing a systemic immune response comprising the steps of providing cells of at least one allogenic cell line providing at least one tumor associated gangliosides, two cytokines, one heat shock protein, and administering in an amount effective to induce a response to the antigen, classified in class 530, subclass 351, for example. **Please note if this group is selected further**

select one tumor associated ganglioside (i.e. GD-2, GD-3, GM-2, GM-3, GD-1B, or GT-1B), one cytokines (i.e. GM-CSF, IL-2, IL-4, IL-12, or TNF-α), and one heat shock protein (i.e. HSP-60, -70, or –90) to be examined on the merits, and amend the claims accordingly, see below for explanation. THIS ELECTION SHOULD NOT BE CONSTRUED AS A SPECIES ELECTION.

XI. Claims 18 and 32 are drawn to a method of inducing a systemic immune response comprising the steps of providing cells of at least one allogenic cell line providing at least one tumor associated ganglioside, one cytokine, one heat shock protein, leukocyte antigens in common to the subject, and administering in an amount effective to induce a response to the antigen, classified in class 530, subclass 380, for example. **Please note if this group is selected further select one tumor associated ganglioside (i.e. GD-2, GD-3, GM-2, GM-3, GD-1B, or GT-1B), one cytokine (i.e. GM-CSF, IL-2, IL-4, IL-12, or TNF-α), and one heat shock protein (i.e. HSP-60, -70, or –90) to be examined on the merits, and amend the claims accordingly, see below for explanation. THIS ELECTION SHOULD NOT BE CONSTRUED AS A SPECIES ELECTION.**

XII. Claims 18 and 38-39, drawn to a method of inducing a systemic immune response comprising the steps of providing cells of at least one allogenic cell line providing at least one tumor associated ganglioside, one cytokine, one heat shock protein, a melanoma-associated antigen, and

administering in an amount effective to induce a response to the antigen, classified in class 530, subclass 403, for example. **Please note if this group is selected further select one tumor associated ganglioside (i.e. GD-2, GD-3, GM-2, GM-3, GD-1B, or GT-1B), one cytokine (i.e. GM-CSF, IL-2, IL-4, IL-12, or TNF-α), one heat shock protein (i.e. HSP-60, -70, or -90), and one melanoma-assocaited antigen (MAGE-1, MART-1, or GP-100) to be examined on the merits, and amend the claims accordingly, see below for explanation. THIS ELECTION SHOULD NOT BE CONSTRUED AS A SPECIES ELECTION.**

2. The inventions are distinct, each from the other because of the following reasons:

3. Inventions I-VI and VII-XII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product of the instant invention can be used as an tool or for the isolation of specific antibodies or for in vitro examination of immune type responses.

4. Inventions I-VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions differ one from the other because the products

are composed of different ingredients of which alters the composition's effects and endpoints, thereby making each product patentably distinct.

5. Inventions VII-XII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions differ one from the other because the methods comprise the administration of patentably distinct compositions, wherein the methods all differ by steps, ingredients, effects and outcome, thereby making the methods patentably distinct.

6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

7. Claim 18 link(s) inventions VII-XII. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 18. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is

withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

8. Upon election of Groups I-VI or VII-XII, Applicants are additionally required to elect additional tumor associated ganglioside(s), cytokine(s), heat shock protein, and /or melanoma associated antigen, as indicated above as they apply to group(s). The recited tumor associated gangliosides, cytokines, heat shock proteins, and /or melanoma associated antigens have different structures one from other and the search for the different tumor associated gangliosides, cytokines, heat shock proteins, and /or melanoma associated antigens would be unduly burdensome. This requirement is not to be construed as a requirement for an election of species, since each of the tumor associated ganglioside(s), cytokine(s), heat shock protein, and /or melanoma associated antigen recited in alternative form has different structures, functions and constitutes an independent and patentably distinct invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 703-305-3586. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Christopher Yaen
Art Unit 1642
September 29, 2003

ANTHONY C. CAPUTA
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600